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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/463,590 04/20/00 LANDRY

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| EXAMINER |
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HM22/0604

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| DECL. OLY. A | |
| ART UNIT | PAPER NUMBER |

1644

DATE MAILED:

06/04/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/463,590

Applicant(s)

Landry, Samuel J.

Examiner

DeCloux, Amy

Art Unit

1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 45-57 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-19 and 45-57 are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☒ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. _____.
- ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot Program. If you have any questions or suggestions, please contact Paula Hutzell, Supervisory Patent Examiner at paula.hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

1. Applicant's submission of the instant application as a 371 is acknowledged, however Claim 1 does not provide a technical feature that is distinguished over the prior art, as evidenced by Abrams et al (Seminars in Oncology, 23(1):118-134 (1996)), (IDS), who teach a method for stimulating an immune response specific toward a naturally occurring protein in an animal having an immune system including T cells, said method comprising administering to said animal an altered protein derived from said naturally occurring protein, wherein an unstable polypeptide segment has been inserted by artifice into said altered protein (see entire article, including Tables 3 and 4 and Figure 1). Therefore, the instant invention lacks Unity of Invention.

2. A restriction is required under 35 USC 121 and 372 between one of the following groups:

I. Claims 1-8 and 11-19, drawn to a method for stimulating an immune response specific toward a naturally occurring protein in an animal having an immune system including T cells, said method comprising administering to said animal an altered protein derived from said naturally occurring protein, wherein an unstable polypeptide segment has been inserted by artifice into said altered protein, classified in Class 424, subclass 185.1,

II. Claims 9-19, drawn to a method for increasing the immunogenicity of a naturally occurring protein, said method comprising inserting by artifice into said naturally occurring protein an unstable polypeptide segment to produce an altered protein, classified in Class 514, subclass 2,

III. Claims 45-57, drawn to a substantially pure antigen comprising an unstable polypeptide segment inserted by artifice, classified in Class 530, subclass 350.

Note: The inventions of Claims 11-19 will be examined only to the extent of the elected invention.

3. The inventions are distinct, each from the other because:

4. Invention III and Invention I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed, a substantially pure antigen comprising an unstable polypeptide segment inserted by artifice, can be used in materially different processes such as monoclonal antibody production using the phage display procedure, as well as the recited method for stimulating an immune response specific toward a naturally occurring protein in an animal having an immune system including T cells, said method comprising administering to said animal an altered protein derived from said naturally occurring protein, wherein an unstable polypeptide segment has been inserted by artifice into said altered protein.

5. Inventions I and II are different methods because they have different process steps and endpoints; The method of Invention I is drawn to method of administering an altered peptide while the method of Group II is drawn to a method for increasing the immunogenicity of a naturally-occurring protein. Accordingly, Inventions I and are patentably distinct from each other.

6. Invention I and Invention III are related as a process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the process, of inserting by artifice into said naturally occurring protein an unstable polypeptide segment to produce an altered protein, can be used to make other and materially different product, such as a protein with no increase in immunogenicity, by by inserting a gpi-anchor domain into said protein, to produce an altered protein.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. This application contains claims directed to more than one embodiment of the generic invention. These embodiments are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

9. Irrespective of whichever group applicant may elect, applicant is further required

under 35 U.S.C. 121:

- A To elect a **specific embodiment**: of a **specific** altered protein, a **specific** alteration of a **specific** naturally occurring protein of a **specific** animal,
 - B To elect a **specific embodiment**: of the recited unstable polypeptide segment, wherein a **specific** number of amino acid residues are inserted in said unstable polypeptide segment as recited in claim , wherein said polypeptide sequence is recognized by a **specific** protease a cell-derived antigen, wherein said polypeptide sequence has one of the **specific** properties recited in claims 14, 18, 49, and 53 and wherein said altered protein comprises an epitope for a **specific** immune cell such as a T cell as recited in claim 15, (if T cell is selected then a **specific** type of T cell is requested IE T helper or T killer))
10. If Group III is elected, applicant is further required to elect a **specific** embodiment of the antigen of claim 45, such as a tolerogen as recited by claim 57 or a vaccine as recited in claim 56.
11. Applicant is required, in response to this action, to elect a specific embodiment to which the claims shall be restricted if no generic claim is finally held to be allowable. The response must also identify the claims readable on the elected embodiment, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.
12. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional embodiments which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected embodiment. MPEP § 809.02(a).
13. The following claim(s) are generic: claims 1, 9, 14, 18, 45, 49, and 53.
14. The embodiments listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the embodiments lack the same or corresponding special technical features for the following reasons:
15. The different species of the altered proteins differ with respect to their structures and physicochemical properties and are therefore patentably distinct.
16. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one

claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

17. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. a message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located In Crystal Mall 1. The faxing of such papers must conform with the notice published In the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.
Patent Examiner
Group 1640, Technology Center 1600
June 1, 2001

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ART UNIT 182 1644